



Food and Drug Administration
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August 27, 2014

Professional Disposables International, Inc.
Ms. Elizabeth Ernst
Senior Director, Regulatory & Medical Affairs
Two Nice-Pak Park
Orangeburg, NY 10962

Re: K132380
Trade/Device Name: Prevantics® Device Swab
Regulation Number: Unclassified
Regulation Name: Pad, Alcohol, Device Disinfectant
Regulatory Class: Unclassified
Product Code: LKB
Dated: July 31, 2014
Received: August 1, 2014

Dear Ms. Ernst:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,

Respiratory, Infection Control and

Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K132380

Device Name
Prevantics® Device Swab

Indications for Use (Describe)

Prevantics® Device swab contains a 3.15% Chlorhexidine Gluconate and 70% (v/v) Isopropyl Alcohol swab is intended for use to disinfect needleless access sites prior to use.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Sajjad H. Syed -S

Digitally signed by Sajjad H. Syed -S
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ou=People, cn=Sajjad H. Syed -S,
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K132380

Prevantics® Device swab

Section 5: 510(K) Summary Statement 21(CFR 807.92)

Professional Disposables International, Inc.

Section 5: 510(K) Summary Statement 21(CFR 807.92)

510 K Summary	K132380
Manufacturer Name	Professional Disposables International, Inc.
Contact Name	Elizabeth Ernst
Title	Senior Director, Regulatory & Medical Affairs
Postal Address:	100 Phillips Parkway, Montvale, NJ 07645
Fax:	845-398-5347
Date:	7/29/2014
Device Proprietary Names	Prevantics® Device swab
Device Common or Usual Name	Chlorhexidine Gluconate (3.15%)* and Isopropyl Alcohol (70%) Swab
Classification Code	LKB
Classification Panel	General Hospital
Regulation Number	N/A
Predicate Device	Substantial equivalence is claimed to the following devices as related to intended use and design characteristics:
	Curos® Port Protector, Ivera Medical Corp. (K080466)
	BD Alcohol Swab, BD Medical – Medical Surgical Systems (K121655)
Description of the Device	The Prevantics® Device swab is available as a 2 in. x 2 in. swab which contains a 1mL solution (3.15% Chlorhexidine Gluconate and 70% (v/v) Isopropyl Alcohol). The product is intended for single, non-sterile use and is not made with natural rubber latex. The subject device is not intended to treat existing infections. The device is not intended to have any effect on contaminated infusion solutions. The subject device is composed of materials that have been successfully and safely used in medical devices including the predicate devices.
Intended Use of the Device:	Prevantics® Device swab is intended for needleless access site disinfection.
Technological Characteristics	The Prevantics® Device Swab has a similar intended use as its predicate device for disinfecting needleless access sites with the home or healthcare facility. It is provided non-sterile and is constructed with 3.15% chlorhexidine gluconate and the same 70% isopropyl alcohol as its predicate devices. It varies in technological characteristics as compared to two (2) of the predicate devices as the subject device is a nonwoven pad saturated with chlorhexidine gluconate (3.15%) and isopropyl alcohol (70%) and the predicate devices are either an alcohol pad (BD Alcohol Pad) or contain an alcohol pad-like sponge within a rigid cap design like Ivera's Curos® Port Protector.

Prevantics® Device swab
Section 5: 510(K) Summary Statement 21(CFR 807.92)
Professional Disposables International, Inc.

510K Number		K121655	K080466
Product Code	LKB	LKB	LKB
Device Name	Prevantics® Device Swab	BD Alcohol Swab	Curos® Port
Manufacturer	Professional Disposable International Inc	BD Medical – Medical Surgical Systems	Ivera Medical Corporation
Intended Use	When used for scrubbing for 5 seconds and drying for 5 seconds, Prevantics® Device Swab (a single use device) will disinfect needleless access sites prior to access.	Is a single use, sterile device containing 70% Isopropyl alcohol. When used for scrubbing for 5 seconds and allowing drying for 5 seconds, the device will disinfect needleless access sites prior to use.	Is a device containing 70% alcohol, intended for use on swabbable luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. The device will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed.
Additional Claims	Not made with natural rubber latex		
Antimicrobial Agent	Chlorhexidine Gluconate (3.15%) and Isopropyl Alcohol (70%)	70% Isopropyl Alcohol	70% Isopropyl Alcohol
User Population	It may be used in the home or healthcare facility.	It may be used in the home or healthcare facility.	The Curos® Disinfecting Port Protector may be used in the home or healthcare facility.
Sterilization	Non-sterile	Terminally Sterile (Unknown Method)	Gamma Irradiated
Packaging	Individually wrapped	Individually wrapped	Individually wrapped

PDI performed multiple non-clinical tests in support of this 510k submission. Testing included the following: a time kill study involving (two gram positive, two gram negative and 2 fungi) evaluated at multiple time points (15 and 30 sec), a minimum effective concentration (MEC) study (tested at 15 and 30 seconds) and a simulated use study.

Time-Kill Study

A time-kill study was performed (based on ASTM E2315 – 03(2008) Standard Guide for Assessment of Microbial Activity Using a Time-Kill Procedure) to determine how rapidly and effectively Prevantics® Device Swab kills a variety of microorganisms. Three (3) lots Prevantics® Device Swab nearing end of shelf life were tested. (Three lots of the devices were labeled as Chlorascrub. This was the device name prior to rebranding. The devices will be referred to as Prevantics® Device Swabs throughout this document.) Sterile Water for Injection was used as a control.

Six microorganisms were tested: two (2) Gram positive, two (2) Gram negative and 2 fungi (*Staphylococcus aureus* (ATCC #6538), *Enterococcus faecalis* (ATCC #29212), *Escherichia coli* (ATCC #11229), *Pseudomonas aeruginosa* (ATCC #15442), *Candida albicans* (ATCC #10231), and *Candida glabrata* (ATCC #2001). At both 15 and 30 seconds, application of the Prevantics Device Swab solution to the microbial cultures resulted in a $>5.00 \log_{10}$ reduction in CFU/mL for each of the six (6) microorganism listed above.

Microorganism	Test Substance	Mean Log ₁₀ Reduction	
		15 sec	30 sec
Escherichia coli (ATCC #11229)	Chlorascrub Swab Lot No. 11200159	6.07	6.07
	Chlorascrub Swab Lot No. 11200247	6.07	6.07
	Chlorascrub Swab Lot No. 11200251	6.07	6.07
	Sterile Water Lot No. 25065031	0.01	0.02
Staphylococcus aureus (ATCC #6538)	Chlorascrub Swab Lot No. 11200159	6.00	6.00
	Chlorascrub Swab Lot No. 11200247	6.00	6.00
	Chlorascrub Swab Lot No. 11200251	6.00	6.00
	Sterile Water Lot No. 25065031	-0.01	0.06
Candida albicans (ATCC #10231)	Chlorascrub Swab Lot No. 11200159	5.88	5.88
	Chlorascrub Swab Lot No. 11200247	5.88	5.88
	Chlorascrub Swab Lot No. 11200251	5.88	5.88
	Sterile Water Lot No. 25065031	0.07	-0.01

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Microorganism	Test Substance	Mean Log ₁₀ Reduction	
		15 sec	30 sec
Enterococcus faecalis (ATCC #29212)	Chlorascrub Swab Lot No. 11200159	5.76	5.76
	Chlorascrub Swab Lot No. 11200247	5.76	5.76
	Chlorascrub Swab Lot No. 11200251	5.76	5.76
	Sterile Water Lot No. 25065031	0.07	0.14
Pseudomonas aeruginosa (ATCC # 15442)	Chlorascrub Swab Lot No. 11200159	6.46	6.46
	Chlorascrub Swab Lot No. 11200247	6.46	6.46
	Chlorascrub Swab Lot No. 11200251	6.46	6.46
	Sterile Water Lot No. 25065031	0.20	0.23
Candida glabrata (ATCC #2001)	Chlorascrub Swab Lot No. 11200159	6.07	6.07
	Chlorascrub Swab Lot No. 11200247	6.07	6.07
	Chlorascrub Swab Lot No. 11200251	6.07	6.07
	Sterile Water Lot No. 25065031	0.16	0.19

Minimal Effective Concentration (MEC) Study

The minimal effective concentration was examined using a range of dilutions of the Prevantics® Device Swab solution (50 – 90% of nominal). The testing was performed using the same techniques outlined in the Time-Kill Study section above. The microorganisms were limited to one each of Gram positive, Gram negative and fungus (Staphylococcus aureus (ATCC #6538), Escherichia coli (ATCC #11229), and Candida albicans (ATCC #10231)).

At both 15 and 30 seconds, application of the Prevantics® Device Swab solution to the microbial cultures resulted in a >4.00 log₁₀ reduction in CFU/mL for each of the three (3) microorganism listed above. The results indicate that even when diluted to 50% of the nominal concentration, Prevantics Device Swab contains an effective antimicrobial combination.

Simulated Use Study

Additionally, in-vitro data from a Simulated Use Study is also submitted to substantiate performance that the subject device is substantially equivalent to the predicate devices.

		Mean Log10 Reduction (CFU/mL) of Needleless Access Site After 5 Second Application				
Microorganism	Soil	Mean Lot 1	Mean Lot 2	Mean Lot 3	Overall Mean Prevantics	Mean Curos
<i>Candida albicans</i> (ATCC #10231)	No	6.5	6.5	4.9	6.0	6.5
	Yes	6.2	6.2	6.2	6.2	5.3
<i>Candida parapsilosis</i> (ATCC #7330)	No	7.2	5.2	7.2	6.5	2.1
	Yes	4.8	5.4	3.5	4.6	2.5
<i>Escherichia coli</i> (ATCC #25922)	No	5.7	4.9	4.4	5.0	6.3
	Yes	4.8	6.2	3.1	4.7	6.2
<i>Pseudomonas aeruginosa</i> (ATCC #27853)	No	3.3	4.4	4.6	4.1	5.5
	Yes	5.3	4.3	3.1	4.2	5.4
<i>Staphylococcus aureus</i> MRSA (ATCC #33591)	No	5.1	3.6	3.4	4.1	6.5
	Yes	6.6	4.9	4.9	5.5	4.3
<i>Staphylococcus epidermidis</i> MRSE (ATCC #51625)	No	2.3	2.8	2.3	2.4	2.7
	Yes	4.6	3.0	1.3	2.9	2.2
<i>Staphylococcus aureus</i> (ATCC #6538)*	No	5.8	5.5	6.2	5.8	5.5
	Yes	4.7	6.1	5.4	5.4	6.2
<i>Staphylococcus epidermidis</i> (ATCC #12228)*	No	5.5	5.4	5.3	5.4	5.7
	Yes	6.4	5.7	5.5	5.9	5.0

* The testing of both *Staphylococcus aureus* and *Staphylococcus epidermidis* were repeated after the initial results for *Staphylococcus epidermidis* demonstrated a <3 log₁₀ reduction for both predicate and test devices.

The results demonstrate that Prevantics® Device Swab produces a >4.0 log₁₀ reduction in microbial CFU/mL for seven (7) of eight (8) tested microorganisms, regardless of soil conditions. In comparison, the predicate device (Curos® Port Protector) achieved similar >4.0 log₁₀ reduction on six (6) of eight (8) microorganisms. The Curos® Port Protector failed to achieve a >4.0 log₁₀ reduction for *Candida parapsilosis* (ATCC #7330) and *Staphylococcus epidermidis* MRSE (ATCC 51625). The results of the simulated use testing indicate that Prevantics® Device Swab provides substantially equivalent results to the predicate device (Curos® Port Protector).

Determination of Substantial Equivalence:	Summary of Non-Clinical Tests A variety of non-clinical tests were conducted to show the safety and effectiveness of the subject device including comparisons against the predicate devices. Standardized test methods from ISO-10993 were used in this testing and the methods and results are described in the submission.
	Summary of Clinical Tests No new clinical tests were required to support the change.
	The review of the indications for use, the technical characteristics and the results provided from the non-clinical tests performed to satisfy International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (Cytotoxicity, Closed Patch Test, Dermal Irritation, Systemic Toxicity) demonstrate that Prevantics® Device Swabs are substantially equivalent to the predicate devices.

Conclusion Prevantics® Device Swab shares the same indications for use, similar design and functional features and was found to be substantially equivalent to the predicate devices. Prevantics® Device Swab has the same intended use as the predicate; and while it has different technological characteristics, the information submitted to FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed devices.

This summary includes all information necessary and Professional Disposable International Inc will provide any additional information requested by FDA during review of the 510(k).

Professional Disposable International Inc verifies that the following criteria have been met.

- The summary includes only information that is also covered in the body of the 510(k).
- The summary does not contain any puffery or unsubstantiated labeling claims.
- The summary does not contain any raw data, i.e., contains only summary data.
- The summary does not contain any trade secret or confidential commercial information.
- The summary does not contain any patient identification information.